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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/524,130	10/14/2005	Tina Bruce	088212-010701	2464

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GREENBERG TRAURIG, LLP  
MET LIFE BUILDING  
200 PARK AVENUE  
NEW YORK, NY 10166

EXAMINER
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REICHLE, KARIN M

ART UNIT	PAPER NUMBER
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3761

NOTIFICATION DATE	DELIVERY MODE
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07/22/2010

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

SchindlerB@gtlaw.com  
LucasCh@gtlaw.com  
NYIPmail@gtlaw.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/524,130	<b>Applicant(s)</b> BRUCE ET AL.	
	<b>Examiner</b> Karin M. Reichle	<b>Art Unit</b> 3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 23 March 2010.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 26-45 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 26-45 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |                                                                                                            |                                                                                         |
|------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)                        | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____                                                |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 3-23-10 has been entered.

### ***Specification***

2. The disclosure is objected to because of the following informalities: 1) The Summary of the Invention section, i.e. a description of the claimed invention, and the invention of the claims should be commensurate in scope, see 608.01(d).

Appropriate correction is required.

3. The amendment filed 1-21-09 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: the abstract.

Applicant is required to cancel the new matter in the reply to this Office Action.

The abstract is the same as the claim 18 filed 5-9-08. Therefore, it still sets forth a method for preventing breast milk leakage in female humans consisting of placing a reusable, washable, thin, flexible, breathable, liquid impervious shield having an exterior frame laminated

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to an inner membrane against a nipple of a lactating human female; and depressing the nipple, wherein the inner membrane of the shield contacts the nipple. However these are not the steps, i.e. the method, for preventing/controlling breast milk leakage in human females, see, e.g. at page 1, lines 4-5, page 2, lines 4-5, page 2, line 30-page 3, line 1, page 3, lines 1-2, 4-6, 12-17, 21-24, 24-25, and 26-29, page 3, line 31-page 4, line 2 and page 7, lines 16-20 of the description. If Applicant maintains such abstract, the portion of the originally filed application, e.g. page number, line number, which provides support for such should be set forth. See MPEP 714.02, second to last paragraph.

#### ***Claim Objections***

4. Claims 26-45 are objected to because of the following informalities: In claims 26 and 30, “that contacts against” should be --adapted to contact--. This also applies to similar language in claims 33, 37 and 41. Appropriate correction is required.

#### ***Claim Language Interpretation***

5. Since no claim terminology has been explicitly defined in the application the terminology will be given its usual, i.e. dictionary, definition.

#### ***Claim Rejections - 35 USC § 102***

6. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

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7. Claims 26-27 and 30-31 are rejected under 35 U.S.C. 102(b) as being anticipated by Furuno et al '195 as evidenced by Farrell '672.

Claim 26: See the Claim Language Interpretation section supra and '195 at the Figures, the abstract, col. 1, lines 20-23, 26-29, and 52 -63, col. 2, lines 7-13, and 24-65 and col. 3, lines 16-18 and claims, i.e. '195 teaches a re-useable nipple cover sized and shaped to cover the nipple comprising a body 1, see also discussion infra, with an inner layer 3 that is adapted to contact the nipple and has a thickness of between 10 and 20 mils, see, e.g., col. 4, lines 16-17 and col. 1, lines 57-58, i.e. greater than 8 mils, and MPEP 2131.03, with "sufficient specificity", and an outer layer 2 secured to an outer surface of the inner layer, the body having a total thickness of 20-90 mils, i.e. .02 to .09 inches or .5 to 2.25 mm, see, e.g., again col. 4, lines 16-17 and col. 1, lines 57-58, i.e. greater than 8 mils, and MPEP 2131.03, with "sufficient specificity", e.g. outer layer can have thickness 8-24 mils and inner layer is thicker than outer layer, e.g. total body thickness is greater than 16 mils. Claim 26 further requires 1) the body be silicone rubber, and 2) the body be a reusable breast shield sized to cover a nipple, areola, and surrounding breast area of a human female with an inner layer that contacts against the nipple, areola, and surrounding breast area, i.e. a property, function or capability of the claimed structure. With regard to 1), see, e.g., col. 1, lines 54-55 with regard to the outer layer and col. 2, lines 36-45, esp. 43-44 as evidenced by '672 at col. 15, lines 37-41, i.e. "KE1052(A-B)" is a RTV silicone rubber. With regard to 2), while '195 as discussed supra teaches a body which is sized and shaped to cover the nipple and an inner surface which contacts the nipple, it does not appear to explicitly set forth the capability, function or property of the body to further cover the aureola and a portion of surrounding breast area of a human female breast and the inner layer to contact such. However

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see the discussion of claim 31-32 *infra* and the Figures, i.e. the same size and shape as claimed. Therefore, at the very least, there is sufficient factual evidence for one to conclude that such body/inner layer of such same size and shape of '195 would also inherently include the same capability, i.e. coverage of/contact with the aureola and a portion of surrounding breast area of a human female breast. See MPEP 2112.01.

Claim 27: The inner layer is constructed of a first silicone rubber, see, e.g., col. 2, lines 34-45, a "gel", and the outer layer is constructed of a different second silicone rubber, see col. 2, lines 7-11.

Claim 30: The inner layer includes a smooth inner surface that contacts against the nipple, areola, and surrounding breast area, see, e.g., the discussion of claim 1 and the Figures of '195.

Claim 31: The shield has an elliptical curvature, see, e.g. Figures of '195.

8. Claims 28, 33-34, 36-42 and 44-45 are rejected under 35 U.S.C. 102(b) as being anticipated by Furuno et al '195 as evidenced by Farrell '672, the instant application at page 7, lines 7-8, Ikeno '890 and Muramatsu et al '581.

Claim 33: See discussion of claims 26-27 and 30-31 *supra*. This claim also requires the first layer have a durometer of 10 or less Shore A and the second layer has a durometer of between 0 and 100 Shore A. '195 as evidenced by '672 teaches a first/inner layer 3 which comprises a silicone rubber "gel" compound and such "gel" has a stiffness of less than 10 durometer Shore "A", i.e. 0 durometer Shore "A", with "sufficient specificity", note again MPEP 2131.03, as evidenced by page 7, lines 7-8 of the instant application, '890 at col. 2, lines 62-65 and '581 at col. 2, lines 18-22, and '195 teaches a second/outer layer 2 of silicone rubber, see

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col. 2, lines 7-12, i.e. not a “gel”, i.e. greater than 0 durometer Shore “A”, which has a stiffness of between 0 and 100 or less durometer Shore "A" with “sufficient specificity”, note again MPEP 2131.03, as evidenced by page 7, lines 7-8 of the instant application, ‘890 at col. 2, line 62-col. 3, line 6 and ‘581 at col. 2, lines 18-26. Note also paragraph 13 *infra*.

Claims 28, 34, 41: See the discussion of claim 33, i.e. the second/outer rubber layer includes a greater durometer than the first/inner gel layer.

Claims 36-40, 42 and 44-45: See discussion of claims *supra*.

### ***Claim Rejections - 35 USC § 103***

9. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

10. Claim 32 is rejected under 35 U.S.C. 103(a) as being unpatentable over Furuno et al ‘195.

The shield has a diameter in the range of 1.0 to 5.0 inches, see col. 1, lines 60-63, i.e. the diameter is 1.4 to 2.6 inches. Note again MPEP 2131.03, I. Claim 32 further requires the shield have a depth in the range of between 0.5 to 2.5 inches. While ‘195 teaches a shield having a depth, see Figures and, e.g., col. 2, lines 7-48, it does not disclose the specific depth range as claimed. It is further noted that the instant specification does not disclose the criticality of such a range of depth as claimed. Still further ‘195 not only recognizes that such depth, i.e. shape, is a result effect variable, see, e.g., col. 2, lines 7-48 and MPEP 2144.05, but teaches a re-useable curved body shaped to a portion of the breast for covering/shielding the nipple like the disclosed invention. Therefore, since the general conditions of the claim are disclosed by ‘195, it is not

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inventive to discover the optimum ranges by routine experimentation, In re Aller, 105 USPQ 233 (CCPA 1955).

11. Claims 29, 35 and 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Furuno et al '195 as evidenced by Farrell '672, alone or such and the instant application at page 7, lines 7-8, Ikeno '890 and Muramatsu et al '581.

These claims require the inner and outer layers are or body is translucent. While '195 as evidenced by '672 at col. 15, lines 37-41, i.e. "transparent" and col.2, lines 63-65 of '195 teach a transparent inner/first layer and the inner first layer and second outer layer are indistinct at the boundary therebetween, '195 does not explicitly teach the second outer layer being transparent, i.e. translucent. However, to employ a transparent, i.e. translucent, second/outer layer, and thereby transparent body, on the '195 device if not already would be obvious to one of ordinary skill in the art in view of the recognition that such would provide an indistinguishable boundary between the layers and the desire of such by '195. See also paragraph 13 infra.

### ***Response to Arguments***

12. Applicant's remarks have been carefully considered but are either deemed moot in that the issue discussed has not been repeated or deemed not persuasive for the reasons set forth supra.

### ***Conclusion***

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Note '538 already of record at col. 3, lines 61-63. The prior art not applied also



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teaches disclosed and/or claimed features of the instant invention. Specifically note English abstract of JP '368, col. 1, lines 14-17 of '853, col. 1, lines 9-17, and col. 3, lines 9-27 of '253, paragraph 17 of '903, the paragraph bridging cols. 2-3. of '922 and Sample 1 of '393.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karin M. Reichle whose telephone number is (571) 272-4936. The examiner can normally be reached on Monday-Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

July 16, 2010

/Karin M. Reichle/  
Primary Examiner, Art Unit 3761